

Application No.: 09/484331

Docket No.: ATX-007CP4DV12

REMARKS

This is a Formal Reply to the Communication mailed June 21, 2004 in which Examiner Shukla set forth what he considered to be the substance of the interview conducted by telephone on May 12, 2004. The participants in the interview from the United States Patent and Trademark Office were Examiner Shukla, Supervisory Examiner Reynolds and Biotechnology Patent Specialist Stanton, and the participants for Applicants were Attorney Anne Brown and Dr. Youssef Bennani, Senior Director of Medicinal Chemistry and Drug Discovery, Athersys, Inc.

I. Procedural History

At the outset, Applicants note that the prosecution of the present application has been extensive, a summary of which is set forth below.

Non-Final Office Action On Merits	April 28, 2000
Response	August 28, 2000
Final Office Action On Merits	November 17, 2000
Interview	January 5, 2001
CPA and Preliminary Amendment	January 18, 2001
Non-Final Office Action On Merits	April 11, 2001
Response	August 13, 2001
Interview	August 30, 2001
Second Non-Final Office Action On Merits	October 25, 2001
Interview	April 17, 2002
Response	April 25, 2002
Final Office Action On Merits	January 13, 2003
Interview	May 16, 2003
Response	July 11, 2003
Advisory Office Action	August 5, 2003
New Non-Final Office Action	December 23, 2003
Interview	May 12, 2004
Response	June 23, 2004

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II. Interview Summary

The Examiner's Interview Summary dated June 21, 2004, summarized the substance of the interview held on May 12, 2004, as follows: "The new matter and enablement rejections were discussed. Ms. Brown indicated that she did not understand the issues raised in the office action. Examiner Shukla reiterated the issues set forth in the office action. Mr. Bennani explained the process. BPS Stanton and Reynolds [sic] advised applicants to file response [sic] to the outstanding office action and appropriate action would be taken."

Applicants wish to clarify the substance of the interview with particularity. At the outset, Applicants point out that Ms. Brown clearly understood the basis for the written description rejection because the basis for this rejection had been clearly set forth by Supervisory Examiner Reynolds in a previous interview. However, Ms. Brown did not understand the reason for re-presenting an enablement rejection on grounds that she believed had already been resolved earlier in the prosecution of the application.

A. Written Description

The basis of the current written description requirement was raised for the first time by Supervisory Examiner Reynolds in the telephonic interview held on May 16, 2003. The basis for this rejection had not been previously set forth in a written office action. Although Applicants pointed this out in the May 16, 2003 interview, Applicants nevertheless agreed to include a rebuttal of this new rejection in their response to the Final Office Action dated January 13, 2003. Accordingly, Applicants' Response filed July 11, 2003, presented a third party Expert Declaration addressing and rebutting the grounds for the new written description rejection.

In the latest Non-Final Office Action dated December 23, 2003, for which the latest interview was directed, Examiner Shukla issued a written description rejection which formally set forth the basis previously presented orally by Supervisory Examiner Reynolds. In the May 12, 2004 interview, Applicants' attorney pointed out that a Declaration addressing the basis for this rejection had already been presented by Applicants in the Response filed July 11, 2003, and that the current non-final Office Action did not acknowledge the Declaration. BPS Stanton then

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indicated that the Examiner Shukla should consider the Declaration. BPS Stanton also stated that it would not be necessary for Applicants to re-present the Declaration, but that they should refer to it in their next response. Applicants have now done so in the Response filed June 23, 2004.

B. Enablement

Confusion about certain grounds for non-enablement was not resolved in the latest interview. These grounds for rejection had been previously presented in the very first Office Action dated April 28, 2000 (pgs. 4-7), and were the subject of discussion during an interview that Applicants conducted on January 5, 2001, at the USPTO with Examiner Shukla and Primary Examiner Scott Priebe. During this interview, Primary Examiner Priebe suggested a straightforward amendment to overcome the rejection. Applicants amended the claims accordingly in the Preliminary Amendment filed January 18, 2003, and the Examiner withdrew the rejection (first non-final Office Action dated April 11, 2001).

However, this rejection re-appeared with the same grounds in a later Office Action dated October 25, 2001 (paragraph spanning pgs 8-9), and these grounds continue to be asserted even in the last Office Action dated January 23, 2004 (paragraph spanning pgs 5-6 and first paragraph of page 6). Dr. Bennani attempted to address these grounds for rejection in a telephonic interview June 3, 2003, but was diverted by Supervisory Examiner Reynolds when she advised that the real issue was not enablement but written description. Supervisory Examiner Reynolds indicated that if written description were to be resolved, the enablement rejection would also be settled.

In the May 12, 2004, interview Ms. Brown attempted to address the substance of the grounds of non-enablement in order to understand why they had been re-presented, *i.e.*, why the amendment was no longer considered sufficient. Examiner Shukla insisted that old grounds for rejection had not been re-presented. However, Dr. Bennani and Ms. Brown were unable to clarify the difference(s) between the old grounds for rejection and those in the latest Office Action, or why the amendment was no longer sufficient to overcome those specific grounds. Applicants have sincerely attempted to address the issue of enablement in the Response filed June 23, 2004, and are desirous of resolving the remaining issues expeditiously.

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C. Number of Interviews

In the interview, Supervisory Examiner Reynolds strongly advised Applicants' attorney that the number of interviews that have been conducted was excessive, although there have been four non-final office actions from the Examiner and five interviews with the Examiner to discuss each new issue raised. Applicants do not disagree that the prosecution of this application has been lengthy, but believe that the number of interviews to be reasonable in view of the issues raised in each non-final office action. Notwithstanding, Applicants believe that in view of the arguments presented herein and in the Response filed June 23, 2004, that the pending application is in condition for allowance.

Applicants believe no fee is due with this statement. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. ATX-007CP4DV12 from which the undersigned is authorized to draw.

Dated: July 21, 2004

Respectfully submitted,

By 

Cynthia L. Kanik, Ph.D.

Registration No.: 37,320

For

Anne Brown, Ph.D.

Registration No. 36,463

Attorney/Agent For Applicant

LAHIVE & COCKFIELD, LLP

28 State Street

Boston, Massachusetts 02109

(617) 227-7400

(617) 742-4214 (Fax)